Remarks/Arguments

Claims 16, 20 – 24, and 27 – 28 remain in this application. Claims 17 – 19, 25 – 26, and 29 – 35 have been canceled. Claims 16, 22 and 24 have been amended to emphasize the patentable distinctions of applicant's invention over the prior art.

Claim 16, as amended, discloses a method for monitoring the clinical effectiveness of the administration of a formulation comprising one or more therapeutic growth factor proteins in the treatment of coronary artery disease, the method comprising the steps of: (a) selecting a patient displaying symptoms of coronary artery disease; (b) administering at least one dose of an effective amount of a first therapeutic growth factor protein formulation comprising a growth factor protein selected from the group consisting of FGF-1, FGF-2, VEGF, and mixtures thereof by inhalation therapy; (c) obtaining a sample of a biological fluid from the patient displaying symptoms of coronary artery disease; (d) performing an assay of the biological fluid to determine an amount of CPK-MB present in the fluid; (e) determining, based on monitoring the amount of CPK-MB present in the fluid, whether an additional dose of a therapeutic growth factor protein formulation is necessary; (f) depending on the results of the step e), administering one or more additional doses of a second growth factor protein formulation comprising a growth factor protein being selected from the group consisting of FGF-1, FGF-2, VEGF, and mixtures thereof; and (g) repeating steps c) through f) until the assayed levels of CPK-MB in the biological fluid indicates the clinical effectiveness of the administration of the pharmaceutical formulation and amelioration of the symptoms of coronary artery disease in the patient, or until there is a contraindication to continued treatment.

Claim 24, as amended, recites substantially the same limitations as present claim 16, except that present claim 24 discloses a method for use in the treatment specifically of chronic coronary artery disease.

Each of the amendments to the claims is clearly supported by the specification, as originally filed in the Parent application. The present application is a division of the Parent, which has now issued as U.S. Pat. No. 6,759,386.

The Examiner has objected to the specification because of the following informalities: typos "FGB-2" and "BFGF" ([00023]). In order to overcome this objection, entry of the amendments to the specification addressing these errors, as established by page 2 herein, is respectfully requested. The amendments to the specification are clearly supported by the original application.

Accordingly, reconsideration of the objection to the specification as containing typographical errors is respectfully requested.

Claims 16, 24, and 31 have been rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The Examiner states that he was unable to find an art-accepted definition for the term "acute coronary artery disease" in the NIH MeSH National Library of Medicine database, www.dictionary.com, and the University of Newcastle upon Tyne's On-Line Medical Dictionary. Therefore, the Examiner has treated "acute coronary artery disease" as "coronary artery disease", the most relevant and art-accepted term encompassed by the limitation that was located by the Examiner. In order to overcome this rejection, claim 16 has been amended to correspond with the Examiner's suggestions. Additionally, claim 24 has been amended to change the

phrase "acute coronary artery disease" to "chronic coronary artery disease". Claim 31 has been canceled in order to expedite prosecution of the present application.

Accordingly, reconsideration of the rejection of claims 16 and 24 under 35 U.S.C. 112, second paragraph, is respectfully requested.

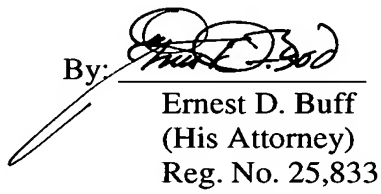
In light of the amendments to independent claims 16 and 24, it is further submitted that present claims 16, 20 – 24, and 27 – 28 patentably define over the cited art relied upon in each of the claim rejections contained by the present Office Action. In particular, applicant respectfully submits that none of the cited references, namely, (i) Spallarossa et al. (15 August 1999) "Evaluation of Growth Hormone Administration in Patients With Chronic Heart Failure Secondary to Coronary Artery Disease." The American Journal of Cardiology 84(4): 430-433; (ii) Vassenelli et al. (December 1987) "Comparison of Different Pharmacological Interventions on Enzymatic Parameters During Acute Myocardial Infarction." Clinical Biochemistry 20(6): 441-447; (iii) Sellke et al. (June 1998) "Therapeutic Angiogenesis With Basic Fibroblast Growth Factor: Technique and Early Results." Ann Thoac Surg 65(6): 1540-1544; (iv) US 6,620,784 B1 (16 September 2003) Ferrara et al.; and (v) D'Souza et al. (October 1978) "The significance of the MB isoenzyme in patients with acute cardiovascular disease with a normal or borderline total CPK activity." Clinical Biochemistry 11(5): 204-209, disclose or suggest the method steps of present claims 16, 20 – 24, and 27 – 28. As amended, these claims collectively require use of a multi-tiered approach for monitoring the clinical effectiveness of the administration, via inhalation therapy, of a formulation comprising one or more therapeutic growth factor proteins in the treatment of coronary artery disease.

Accordingly, reconsideration of the rejection of present claims 16, 20 – 24, and 27 – 28 under 35 U.S.C. §§ 102 (a), 102(b) and 103(a) as being unpatentable over the aforementioned references is respectfully requested.

Conclusion

In view of the amendments to the specification and the claims, and the remarks set forth above, it is respectfully submitted that the present application is in allowable condition. Reconsideration of the rejection and allowance of claims 16, 20 – 24, and 27 – 28, as amended, are earnestly solicited.

Respectfully submitted,
Wayne P. Franco

By: 
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